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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/834,434	04/13/2001	Mark A. Emalfarb	3123-4006	5903

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EXAMINER

WESSENDORF, TERESA D

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 02/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/834,434	EMALFARB ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	T. D. Wessendorf	1639	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 October 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) 6-8 and 13-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 9-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☒ None of:  
         1. ☒ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
     a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Election/Restrictions***

Applicant's election with traverse of Group II claims 3-5 and 10-23 is acknowledged. The traversal is on the ground(s) that the search and examination of the entire application can be made without serious burden, even though it includes claims to independent or distinct inventions. (MPEP 803). Applicants submit that all claims of groups I-IX can be examined without undue burden, in particular, the restrictions of groups I, II, VII and VIII. Applicants point out that claim 3 contains all of the limitations of claim 1, with the additional limitations of screening and isolating a DNA molecule of interest. Therefore, a search that finds claim 1 allowable would also very likely be sufficient to find claim 3 allowable. In addition, claims 46 and 47 contain the same limitations found in claim 1 with respect to the steps involved for making a library of transformed filamentous fungi. Therefore, a search that finds claims 46 and 47 allowable would also very likely be sufficient to find claim 1 allowable. For these reasons, Applicants submit there is no undue burden associated with searching on the subject matter of the claims contained in groups I, II, VII and VIII.

Upon consideration of applicants' request and the restriction requirement, Group I will be examined with the elected group II. However, groups VII and VIII would not be combined because as applicants state these are drawn to the compound library and the transformed filamentous fungi. Applicants' arguments are not persuasive. The examination of these compounds would be a burden to examine. The search involves not only U.S. patents but scientific publications as well. These searches are not co-extensive. Furthermore, the patentability determinations of a compound claim are different from the method claims.

The requirement is still deemed proper and is therefore made FINAL.

Applicants' election of the species, subgroup E, the Hyphal fragment is noted.

Claims 6-8 and 13-48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement.

***Status of Claims***

Claims 1-48 are pending in the application.

Claims 6-8 and 13-48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Claims 1-5 and 9-12 are under examination.

***Specification***

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See page 14, lines 1-2. See MPEP § 608.01.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors (typographical, grammatical and idiomatic). Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

***Drawings***

The drawings are objected to because there is no sequence identifier number for the sequence shown in Figure 12. A drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-5 and 9-12 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claimed method of expressing a plurality of proteins encoded by a library of DNA vectors is a non-statutory subject matter. The claimed method is neither a method of making or a method of using. It is not clear as to the utility of the method of simply expressing a plurality of proteins. Cf. with claims 3-5 which employs this intermediate process to the method of producing a compound. [It appears that claims 3-5 which include this method fulfill the utility requirement. Therefore, it is suggested that applicants incorporate the process steps to claims 3-5].

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***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 and 9-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is unclear as to the process step of "providing" which is not a positive, manipulative process step. It is unclear whether it relates to a step of making the fungal in suspension or its transferable productive elements or an already prepared (i.e., supplied by applicants) fungi, especially in connection with step (e). "Plurality of the individual fungal" and "at least one heterologous protein encoding nucleic acid" lack antecedent basis of support from the preceding steps.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Borchert et al (6,518,042).

Borchert discloses at col.2, line 55 up to col.3, line 41; col. 8, lines 36-30 a method for production of a polypeptide of interest comprising the steps of a). preparing a filamentous fungal cell population wherein individual cells in the population comprise individually different DNA sequences of interest representing a DNA library of interest comprising placing individually different DNA sequences of interest in a filamentous fungal cell population; b). growing the population of the fungal cells for a period of time allowing an individual DNA sequence of interest in the population to be duplicated and wherein the DNA sequences of interest encode a polypeptide of interest and c). selecting from the resultant population of filamentous fungal cells the desired polypeptide of interest. See the specific Examples at col. 11, line 20 up to col. 16, line 63. See specifically the spore-suspension



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of the fungal cells being made which will read on the broad claimed transferable reproductive elements. Accordingly, the specific process steps of Borchert using specific components of e.g., fungal cell and nucleic acids fully meet the broad claimed method.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5 and 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borchert et al (6,518,042) or applicants' disclosure of known prior art (as applied to the elected species, hypal fragments).

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Borchert is discussed above. Applicants disclose at col. 2, [0014] up to col. 4, [0023] that ".....Lambowitz, in U.S. patent 4,486,533, discloses an autonomously replicating DNA vector for filamentous fungi and its use for the introduction and expression of heterologous genes in Neurospora..... Vectors for transformation on Neurospora are disclosed in U.S. patent 5,834,191.....Homogeneous distribution of loose mycelium, with pronounced branching, was described as a particularly desirable morphology.....Mutants with at least 10% greater hyphal branching are particularly claimed....."

Borchert et al or the prior art disclosed by applicants does not teach hypal fragments (some of the prior art disclosed by applicants described this fragment.) However, Shuster discloses at col. 4, line 38 up to col. 5, line 5 said mutant cells having a more extensive hyphal branching. Shuster further discloses that the mutant cells have an improved property for production of a heterologous polypeptide than the parent cell, when the mutant and parent cells are cultured under the same conditions. The mutants possess improved growth characteristics in fermentation where the morphology gives rise to lower viscosity in the fermenter, in turn leading to easier mixing, better aeration, better growth, and ultimately, enhanced yield of heterologous polypeptide produced by the mutant strain relative to the parent

strain. In a preferred embodiment, the improved property is selected from the group consisting of (a) increased yield of the heterologous polypeptide, (b) improved growth, (c) lower viscosity, and (d) better secretion. In a most preferred embodiment, the improved property is increased yield of the heterologous polypeptide. In another most preferred embodiment, the improved property is improved growth. In another most preferred embodiment, the improved property is lower viscosity. In another most preferred embodiment, the improved property is better secretion. Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a hypal fragment in the method of Borchert or anyone of the prior art disclosed by applicants in the manner as taught by Shuster et al. One would have been motivated to use a hypal fragment rather than the whole cell for the lower viscosity and better secretion of the heterologous DNA as taught by Shuster.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be

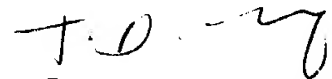
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reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-7924.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



T. D. Wessendorf  
Primary Examiner  
Art Unit 1639

Tdw

January 23, 2004